

she has such access.<sup>3</sup> In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access from the HHS Secretary or Administrator before he/she works in or visits areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins.

(b) Refresher training must be provided annually.

(c) A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

#### § 73.16 Transfers.

(a) Except as provided in paragraphs (c) and (d) of this section, a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by CDC or APHIS prior to the transfer.<sup>4</sup>

(b) A transfer may be authorized if:

(1) The sender:

(i) Has at the time of transfer a certificate of registration that covers the particular select agent or toxin to be transferred and meets all requirements in this part,

(ii) Meets the exemption requirements for the particular select agent or toxin to be transferred, or

(iii) Is transferring the select agent or toxin from outside the United States and meets all import requirements.

(2) At the time of transfer, the recipient has a certificate of registration that includes the particular select agent or toxin to be transferred and

meets all of the requirements of this part.

(c) A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from CDC or APHIS provided that, at least seven calendar days prior to the transfer, the sender reports to CDC or APHIS the select agent or toxin to be transferred and the name and address of the recipient.

(d) On a case-by-case basis, the HHS Secretary may authorize a transfer of a select agent or toxin, not otherwise eligible for transfer under this part under conditions prescribed by the HHS Secretary.

(e) To obtain authorization for transfer, APHIS/CDC Form 2 must be submitted.

(f) The recipient must submit a completed APHIS/CDC Form 2 within two business days of receipt of a select agent or toxin.

(g) The recipient must immediately notify CDC or APHIS if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package containing select agents or toxins has been damaged to the extent that a release of the select agent or toxin may have occurred.

(h) An authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (e.g., change in the certificate of registration for the sender or recipient, change in the application for transfer).

(i) The sender must comply with all applicable laws concerning packaging and shipping.

#### § 73.17 Records.

(a) An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include:

(1) Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant organisms) held in long-term storage (placement in a system designed to ensure viability for

<sup>3</sup>The training need not duplicate training provided under the OSHA Bloodborne Pathogen Standard set forth at 29 CFR 1910.1030.

<sup>4</sup>This section does not cover transfers within an entity when the sender and the recipient are covered by the same certificate of registration.